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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,252

Applicant(s)

ELLINGTON, ANDREW

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-10,12,15,19-22,24,25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-10,12,15,19-22,24,25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 September 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 28 September 2004 in which claims 1, 15 and 28 were amended and claims 11 and 23 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 30 March 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1, 6-10, 12, 15, 19-22 24-25 and 28 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6-10, 12, 15, 19, 25 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Stanton et al (U.S. Patent No. 6,680,377 having priority to 60/134,330 filed 14 May 1999).

Regarding Claim 1, Stanton et al teach a method of transducing a conformational change of a signaling aptamer upon ligand binding, the method comprising the steps of covalently coupling a reporter (#24) within an aptamer in proximity to ligand binding site, such that the reporter does not interfere with binding (Fig. 3c-d) wherein reporter replaces a nucleic acid residue (Column 13, lines 1-10) and wherein the ligand is not a nucleic acid molecule (Column 3, lines 56-64). Stanton et al teach the method further comprising placing the aptamer in solution, contacting the aptamer with the ligand to bind ligand to the aptamer, thereby inducing conformational change in the aptamer and transducing the change to a detectable signal increase generated by the reporter (Column 12, lines 34-67 and Example 1, Column 22, lines 40-Column 23, line 30). While Stanton et al immobilize the aptamer, their contacting is performed in solution as claimed (Column 22, lines 63-67).

Regarding Claim 6, Stanton et al disclose the method wherein the coupling occurs during chemical synthesis or post-transcription (Column 9, lines 50-58).

Regarding Claim 7, Stanton et al disclose the reporter is a dye (Column 9, line 50).

Regarding Claim 8, Stanton et al disclose the reporter is fluorescent dye (Column 9, line 61).

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Regarding Claim 9, Stanton et al disclose the reporter is fluorescein (Column 13, lines 1-5).

Regarding Claim 10, Stanton et al disclose the method wherein the aptamer is RNA, DNA, modified RNA or modified DNA (Column 3, lines 59-64).

Regarding Claim 12, Stanton et al disclose the ligand is in solution i.e. the sample containing the ligand is dissolved in saline buffer (Column 22, lines 63-67).

Regarding Claim 15, Stanton et al teach a method of transducing a conformational change of a signaling aptamer upon ligand binding, the method comprising the steps of covalently coupling a fluorescent dye (#24, Column 9, line 59-63) within an aptamer in proximity to ligand binding site, such that the reporter does not interfere with binding (Fig. 3c-d) wherein reporter replaces a nucleic acid residue (Column 13, lines 1-10) and wherein the ligand is not a nucleic acid molecule (Column 3, lines 56-64). Stanton et al teach the method further comprising placing the aptamer in solution, contacting the aptamer with the ligand to bind ligand to the aptamer, thereby inducing conformational change in the aptamer and transducing the change to a detectable signal increase generated by the reporter (Column 12, lines 34-67 and Example 1, Column 22, lines 40-Column 23, line 30). While Stanton et al immobilize the aptamer, their contacting is performed in solution as claimed (Column 22, lines 63-67).

Regarding Claim 19, Stanton et al disclose the reporter is fluorescein (Column 13, lines 1-5).

Regarding Claim 25, Stanton et al disclose the ligand is in solution i.e. the sample containing the ligand is dissolved in saline buffer (Column 22, lines 63-67).

Regarding Claim 28, Stanton et al disclose the method further comprising correlating the fluorescence with the quantity of ligand bound (Abstract, lines 1 and 2 and Column 19, lines 61-67).

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 20-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al (U.S. Patent No. 6,680,377 having priority to 60/134,330 filed 14 May 1999) in view of Szostak et al. (U.S. Patent No. 5,631,146, issued 20 May 1997).

Regarding Claims 20-22 and 24, Stanton et al teach a method of transducing a conformational change of a signaling aptamer upon ligand binding, the method comprising the steps of covalently coupling a reporter (#24) within an aptamer in proximity to ligand binding site, such that the reporter does not interfere with binding (Fig. 3c-d) wherein reporter replaces a nucleic acid residue (Column 13, lines 1-10) and wherein the ligand is not a nucleic acid molecule (Column 3, lines 56-64). Stanton et al teach the method further comprising placing the aptamer in solution, contacting the aptamer with the ligand to bind ligand to the aptamer, thereby inducing conformational change in the aptamer and transducing the change to a detectable signal increase generated by the reporter (Column 12, lines 34-67 and Example 1, Column 22, lines 40-Column 23, line 30). While Stanton et al immobilize the aptamer, their contacting is performed in solution as claimed (Column 22, lines 63-67).

Stanton et al teach their method is useful for the isolate of various non-nucleic acid target molecules (Column 3, lines 56-59) but they do not teach the aptamers are anti-adenosine RNA or DNA aptamer wherein the former is ATP-R-ACI3 and the latter is DFL7-8 and the ligand (target molecule) is adenosine.

However, Szostak et al teach anti-adenosine triphosphate and anti-adenosine DNA aptamers prepared by the same process (Column 4, line 56-column 6, line 9) and they further

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teach anti-adenosine aptamers are especially useful for ATP purification and in vivo quantification (Column 18, lines 31-42). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply anti-adenosine aptamers of Szostak et al to the target detection of Stanton et al for the expected benefits of purification and in vivo quantification of an important target molecule as taught by Szostak et al (Column 18, lines 31-42).

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check

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PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
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December 3, 2004